Paper No. 92

#### THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today

- (1) was not written for publication in a law journal and
- (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

RALPH G. CHILD, PANAYOTA BITHA, JOSEPH J. HLAVKA and YANG-I LIN,

Junior Party, 1

v.

CENEK KOLAR, HANS P. KRAEMER and KONRAD DEHMEL,

Senior Party.<sup>2</sup>

Patent Interference No. 102,408

<sup>&</sup>lt;sup>1</sup>Application 07/358,544, filed May 26, 1989. Accorded the benefit of Application 06/824,404, filed January 31, 1986, now U.S. Patent No. 4,880,790, issued November 14, 1989. Assigned to American Cyanamid Company, Stamford, CT, A Corporation of Maine.

<sup>&</sup>lt;sup>2</sup>Application 06/770,996, filed August 30, 1985, now U.S. Patent No. 4,730,069, issued March 8, 1988. Accorded the benefit of West German Patent Application P 34 32 320.1, filed September 3, 1984. Assigned to Behringwerke Aktiengesellschaft, A Corporation of Germany.

Before DOWNEY, GRON, and HANLON, <u>Administrative Patent Judges</u>.

HANLON, <u>Administrative Patent Judge</u>.

## FINAL DECISION UNDER 37 CFR § 1.658

This is a final decision in Interference No. 102,408 between Child et al. (Child) and Kolar et al. (Kolar). Kolar is the senior party by virtue of having been accorded the September 3, 1984, filing date of West German patent application P 34 32 320.1 in the decision on motions (Paper No. 46).

Count 1, the sole count at issue in this interference, relates to certain organoplatinum compounds and reads as follows:

A compound of the formula I or II

in which  $R^1$  and  $R^2$  independently of one another represent  $H^-(CH_2)_a^-(O^-(CH_2)_b)_c^-O$ , where a=0 to 4, b=1 to 4 and c=1 to 7, an alkoxy or arylalkoxy group with 1 to 20 carbon atoms, an alkane- or aralkanesulfonyloxy group with 1 to 7 carbon atoms or a tetrahydropyranyloxy radical, or  $R^1$  and  $R^2$  together represent an an ether-like manner or an acetal or ketal radical

where  $R^3$  and  $R^4$  independently of one another represent a hydrogen atom, an alkyl group with 1 to 20 carbon atoms or a phenyl group,  $A^1$  and  $A^2$  are identical and represent a hydroxyl group, halide, nitrate, acetate, trifluoroacetate, trifluorosulfonate, perchlorate or sulfate, or  $A^1$  represents

sulfate or carbonate and  $A^2$  represents  $H_2O$ , or  $A^1$  or  $A^2$  together represent the dianion of an organic acid selected from the group consisting of dibasic carboxylic, aconitic, 3- or 4-carboxyphthalic and 3,4-dicarboxyphthalic acid, or  $A^1$  and  $A^2$  together represent a

recurring anionic unit of a polymeric compound selected from the group consisting of dextran sulfate, chondroitin sulfate, galactan sulfate, polyglutamic acid or polyitaconic acid.

The claims of the parties which correspond to Count 1 are as follows (Paper No. 47):

Child: claims 2-12, 33 and 34

Kolar: claim 1

Both parties filed records and briefs, Child also filing a reply brief,<sup>3</sup> and both parties waived the opportunity to present an oral argument at a final hearing (Paper No. 90).

Child's brief raises the following issues (CB1):

- (1) Has junior party Child proven a reduction to practice of the subject matter of the count prior to August 30, 1985?<sup>4</sup>
- (2) Did junior party Child suppress, conceal or abandon an actual reduction to practice of the invention of the count within the meaning of 35 U.S.C. § 102(g)?
- (3) Should the rebuttal testimony of senior party Kolar be stricken as untimely filed?

<sup>&</sup>lt;sup>3</sup>The Child brief, reply brief and record will be referred to throughout this decision as CB, CRB, and CR, respectively, followed by the appropriate page number. Similarly, the Kolar brief will be referred to as KB followed by the appropriate page number.

<sup>&</sup>lt;sup>4</sup>As discussed above, September 3, 1984, Kolar's effective filing date, is the critical date.

- (4) Should the rebuttal testimony of senior party Kolar be stricken as improperly executed?
- (5) If the rebuttal testimony of Kolar is not stricken, does it rebut the priority case of Child?

Kolar's brief raises the following issues (KB1-2):

- (6) Has junior party Child established, by a preponderance of the evidence, an actual reduction to practice of the subject matter of the count prior to Kolar's effective filing date of September 3, 1984?
- (7) Does the testimonial evidence submitted by junior party Child enable the skilled artisan to conclude that the invention of the count was reduced to practice by the junior party prior to Kolar's effective filing date of September 3, 1984?
- (8) Has junior party Child abandoned, suppressed or concealed the invention of the count?
- (9) Has senior party Kolar properly filed the declaration of Dr. Cenek Kolar as rebuttal testimony under 37 CFR § 1.672(b)?
- (10) Does the rebuttal testimony of Dr. Kolar effectively support Kolar's allegations with respect to Child's priority case?

In addition, Child filed a motion to strike the rebuttal testimony of Dr. Cenek Kolar (Paper Nos. 63 and 64) which was opposed by Kolar (Paper Nos. 68 and 69). Kolar filed a motion to suppress evidence under 37 CFR § 1.656(h) (Paper No. 85) which was opposed by Child (Paper No. 89).

### Motion to suppress

Senior party Kolar filed a motion under 37 CFR § 1.656(h) (1993) to suppress certain portions of the Child record. See Paper No. 85. However, whether or not those portions of the Child record are suppressed, the junior party does not prevail in this interference. Therefore, Kolar's motion to suppress is dismissed.

## Priority case of junior party

The dispositive issue in this case is whether junior party Child has established, by a preponderance of the evidence, an actual reduction to practice of the subject matter of the count prior to September 3, 1984, Kolar's effective filing date. Holmwood v. Sugavanam, 948 F.2d 1236, 1238, 20 USPQ2d 1712, 1714 (Fed. Cir. 1991) (requiring junior party to prove priority case by a preponderance of the evidence); see also Bosies v. Benedict, 27 F.3d 539, 541-42, 30 USPQ2d 1862, 1864 (Fed. Cir. 1994) (preponderance of the evidence standard and clear and convincing evidence standard distinguished). As senior party Kolar points out, junior party Child does not rely on conception coupled with diligence

to establish priority of invention (KB4). <u>See Keizer v.</u>

<u>Bradlev</u>, 270 F.2d 396, 397, 123 USPQ 215, 216 (CCPA 1959).

A party establishing an actual reduction to practice of the subject matter of a count must show a reduction to practice of each and every limitation of the count. Newkirk <u>v. Lulejian</u>, 825 F.2d 1581, 1582, 3 USPQ2d 1793, 1794 (Fed. Cir. 1987); Correge v. Murphy, 705 F.2d 1326, 1329, 217 USPO 753, 755 (Fed. Cir. 1983); Parker v. Frilette, 462 F.2d 544, 548, 174 USPQ 321, 325 (CCPA 1972); Szekely v. Metcalf, 455 F.2d 1393, 1396, 173 USPQ 116, 119 (CCPA 1972); Schur v. Muller, 372 F.2d 546, 551, 152 USPQ 605, 609 (CCPA 1967). However, where, as here, the count embraces a number of compounds, a reduction to practice of a single compound within the scope of the count constitutes a reduction to practice of the invention defined by the count for purposes of priority of invention in an interference proceeding. Compare Breuer v. DeMarinis, 58 F.2d 22, 24 n.5, 194 USPO 308, 309 n.5 (CCPA 1977); Mikus v. Wachtel, 504 F.2d 1150, 1152, 183 USPO 752, 753 (CCPA 1974); Den Beste v. Martin, 252 F.2d 302, 304-05, 116 USPQ 584, 586 (CCPA 1954).

Manifestly, a reduction to practice of the subject matter of a count must be independently corroborated. Mikus v.

Wachtel, 542 F.2d 1157, 1159, 191 USPQ 571, 573 (CCPA 1976);

see also Reese v. Hurst, 661 F.2d 1222, 1228, 211 USPQ 936,

(CCPA 1981) ("adoption of the 'rule of reason' has not altered the requirement that evidence of corroboration must not depend solely on the inventor himself").

According to junior party Child, it has proven a corroborated reduction to practice of a compound within the scope of the count in the United States prior to September 3, 1984, Kolar's effective filing date (CB4). In addition to the declarations of inventors Ralph G. Child<sup>5</sup> and Yang I. Lin,<sup>6</sup> junior party relies on the declaration testimony of John C.

 $<sup>^5\</sup>mbox{Declaration}$  of Ralph G. Child dated September 29, 1992 (CR354-64).

 $<sup>^6 \</sup>text{Declaration of Yang I. Lin dated September 28, 1992}$  (CR54-57).

James, Jeffrey B. Medwid, Franz Scheidl, Stanley A. Lang, 10 Bruce Heiser, 11 and Frederick Durr 12 to support a corroborated reduction to practice of seven compounds falling within the scope of the count.

#### <u>Facts</u>

Junior party Child's brief at final hearing fails to effectively aid this panel in understanding its case for priority. See Ernst Haas Studio, Inc. v. Palm Press, Inc., 164 F.3d 110, 112, 49 USPQ2d 1377, 1379 (2d Cir. 1999)

("Appellant's Brief is at best an invitation to the court to scour the record, research any legal theory that comes to mind, and serve generally as an advocate for appellant. We

<sup>&</sup>lt;sup>7</sup>Declaration of John C. James dated September 25, 1992 (CR1-5).

 $<sup>^{8}\</sup>text{Declaration}$  of Jeffrey B. Medwid dated September 29, 1992 (CR80-85).

<sup>&</sup>lt;sup>9</sup>Declaration of Franz Scheidl dated September 30, 1992 (CR189-91).

 $<sup>^{10}\</sup>mbox{Declaration}$  of Stanley A. Lang dated September 29, 1992 (CR218-20).

 $<sup>^{11}\</sup>mbox{Declaration}$  of Bruce Heiser dated September 29, 1992 (CR225-27).

<sup>&</sup>lt;sup>12</sup>Declaration of Frederick Durr dated September 29, 1992 (CR285-89).

decline the invitation."). At best, we ascertain junior party Child's position to be as follows.

The declaration of Ralph G. Child provides a detailed explanation of the preparation and testing of seven platinum compounds said to fall within the scope of the count (CB4). The preparation of the first of these compounds, identified as "compound no. 1"13 and allegedly having the following structure:

is said to be described in Exhibit 1 attached to the Child Declaration (CR355,  $\P$  4; CR365). Exhibit 1 is said to be a copy of page 47 from notebook 12459B (CR355,  $\P$  4).

According to Child, on May 31, 1984, he prepared compound

<sup>&</sup>lt;sup>13</sup>Compound no. 1 was used to prepare the remaining six platinum compounds, i.e., compound nos. 2-7. See KB10; CR370; CR375; CR379; CR384; CR391; CR393.

# no. 1 at Lederle<sup>14</sup> by (CR355):

[T]reating 945 mg. of 3,3-oxetainedimethanamine in 40 cc of water with 820 mg. of sodium acetate and 2.075 g of potassium tetrachloroplatinate. The mixture was stirred for three hours and filtered. The filtered crystals weighed 0.37g; mp 262 dec. and were labeled "A". The filtrate was allowed to stand overnight and then the resulting solid was collected giving 440 mg of product as bright yellow crystals melting at 270-272E which was labeled "B".

Compare CR365 (product labeled "A" described as beige solid having melting point of 262E; product "B" described as bright yellow crystals having melting point of 270-273E). Products labeled "C", "D" and "E" also appear to have been prepared during the process (CR365).

Various notations have been used throughout the record to identify products which appear to be described on page 47 of notebook 12459B. For example, a request for infrared analysis prepared by Ralph G. Child uses the notation "sample no. 12459B-47B" to identify one such compound. See CR356, ¶ 4;

<sup>&</sup>lt;sup>14</sup>American Cyanamid Company, Lederle Laboratories Division, Pearl River, New York, USA (hereinafter "Lederle").

<sup>&</sup>lt;sup>15</sup>Presumably, the notation "12459B-47B" is intended to identify the product labeled "B" on page 47 of Child's notebook 12459B, the preparation of which is described therein. Compare CR365 (product "B" described as "bright yellow crystals wt=0.44 mp 270-273E") with CR366 ("[Stru]cture, Color and State [:] yellow crystals [;] BP or

CR366. In turn, sample no. 12459B-47B was assigned Cyanamid Laboratory (CL) number CL285605. See CR228.

"Samples of the products" described on page 47 of notebook 12459B were said to have been subjected to infrared analysis, elemental analysis, and biological testing for anticancer activity (CR355, ¶ 4). The infrared absorption curve for sample no. 12459B-47B is said to be attached to the James declaration as exhibit O. See CR20; CR3-4, ¶ 9. According to Dr. James, the current supervisor of the spectroscopy group at Lederle (CR1,

## ¶ 3):

I have reviewed each of Exhibits O-R and T-V [(CR20-23 and 25-27)] to compare the structural formula which is written on each Exhibit with the infrared absorption curve and confirm that the infrared curve for each structural formula is consistent with each structural formula  $[(CR4, \P10)]$ .

Exhibits 11 and 12, attached to the Medwid Declaration (CR96 and CR97), were identified as reports of the elemental analyses of sample nos. 12459B-47A<sup>16</sup> and 12459B-47B,

MP [:] 270-273E").

<sup>&</sup>lt;sup>16</sup>Presumably, the notation "12459B-47A" is intended to identify the product labeled "A" on page 47 of Child's notebook 12459B, the preparation of which is described

respectively, requested by Child which identify the amounts of C, H, N, Cl and Pt in both samples. Franz Scheidl was said to have analyzed the amounts of Cl and Pt in sample nos. 12459B-47A and 12459B-47B prior to June 9, 1984. See CR191, ¶ 13; CR192; see also CR96 (sample no. 8406019 corresponds to sample no. 12459B-47A); CR97 (sample no. 8406052 corresponds to sample no. 12459B-47B). However, the evidence relied on by Child is silent as to when either sample was analyzed for C, H, and N.

Finally, sample no. "285605 (12459B 47A)"<sup>17</sup> was said to have been tested for anti-cancer activity. During 1984, Frederick Durr was said to have been "in charge of the group which had the responsibility for testing chemotherapeutic agents for anti-cancer activity" (CR285, ¶ 2). One of the tests which was used at that time was the P 388 test which if

therein. Compare CR365 ("[a]fter stirring for 3 hrs beige solid filtered off and washed separately with water and dried A. wt = 0.37g mp 262E") and CR355, ¶ 4 ("[t]he mixture was stirred for three hours and filtered. The filtered crystals weighed 0.37g; mp 262 dec. and were labeled 'A'.") with CR368 ("RANGE B.P. OR M.P. 262E dec . . . [P]HYSICAL APPEARANCE beige solid").

 $<sup>^{17}\</sup>mbox{As}$  discussed above CL number CL285605 was assigned to sample no. 12459B-47B. See CR228.

positive was accepted as an indication that a compound had anti-cancer activity (CR285,

¶ 2).

According to Durr (CR286, ¶ 3):

During 1984 at Lederle, the standard procedure for carrying out the P 388 test was as follows:

The animals used were BDF 1 mice, all of one sex, weighing a minimum of 17 g and all with a 3 g weight range. There were 5 or 6 mice per test group. The tumor transplant was by intraperitoneal injection of 0.5 ml of diluted ascitic fluid containing 106 cells of lymphocytic leukemia P 388. The test compounds in 0.5 ml of 0.2% Klucel in normal saline were administered intraperitoneally on days 1, 5 and 9 after tumor implantation, at the indicated doses. The mice were weighed and the survivors recorded on a regular basis for up to 30 days. The ratio of survival time for treated (T)/control (C) animals times 100 was calculated. A score of 125 or greater is an indication that the compound was active in the P 388 test. [Compare CR291.]

Exhibit B attached to the Durr declaration is said to report the results of a P 388 test carried out on compound "285605 (12459B 47A)." See CR287, ¶ 7; CR292. The exhibit bears the following dates: (1) "DATE 6/20/84", (2) "Data Entered 7/27/84," (3) "A.J. Hauss 9/25/84," and (4) "9/27/84 H.L. Lindsay."

Additionally, junior party Child relies on the

declaration of Stanley A. Lang, the Head of the Chemistry

Department of the Infectious and Neoplastic Disease Research

Section at Lederle from 1980-1990. According to Lang, Yang-I

Lin, Ralph G. Child, Panayota Bitha and Joseph Hlavka, the

inventors in the Child application involved in this

interference, would prepare and submit monthly reports to Lang

(CR218, ¶ 2). Lang would review these reports and use the

information to prepare a monthly summary which would be

integrated into a monthly report for the Infectious and

Neoplastic Disease Section (CR218-19, ¶¶ 3-4). The summary

for August 1984 reads in part as follows (CR223):

Chemistry (Bitha, Child, Hlavka, Lin, and Sliskovic) As a continuation of our work reported last month on the synthesis of 3,3-bisaminomethyloxetane platinum complexes, dichloro(3,3-bisaminomethyloxetane) platinum complex <u>la</u> reacted with a series of acids by the silver nitrate process to give the following complexes <u>lb-q</u>. The water soluble complex <u>lh</u> (water solubility = 3.5 mg/ml) showed good activity over a wide dose range; i.e., T/C x 100 of 253 at 50 mg/kg and 136 at 3.1 mg/kg.

# <u>Issues (1), (6) and (7)</u>

Based on the record before us, junior party Child has failed to establish an actual reduction to practice of the subject matter of the count prior to September 3, 1984, Kolar's effective filing date. An actual reduction to

practice requires a showing of three elements: (1) production of a composition of matter satisfying the limitations of the count, (2) recognition of the composition of matter, and (3) recognition of a specific practical utility for the composition. Estee Lauder Inc. v. L'Oreal S.A., 129 F.3d 588, 592, 44 USPO2d 1610, 1613 (Fed. Cir. 1997) citing Standard Oil Co. (Indiana) v. Montedison, S.p.A., 494 F. Supp. 370, 206 USPQ 676 (D. Del. 1980), aff'd, 664 F.2d 356, 212 USPQ 327 (3d Cir. 1981); see also Hahn v. Wong, 892 F.2d 1028, 1032-33, 13 USPQ2d 1313, 1317 (Fed. Cir. 1989); <u>Blicke v. Treves</u>, 241 F.2d 718, 720, 112 USPQ 472, 475 (CCPA 1957) (whether a composition of matter must be tested in order to establish an actual reduction to practice, and if so, what tests are necessary must be decided on a case-by-case basis). The evidence relied on by junior party Child fails to satisfy these three elements.

#### A. Compound no. 1

Kolar argues that the evidence submitted by Child does not establish by a preponderance of the evidence that "compound no. 1" was actually prepared and known to have utility as an anti-cancer agent prior to the critical date.

See generally KB12-26.

At the outset, we note that junior party Child has failed to identify which one of products "A", "B", "C", "D" or "E" described on page 47 of notebook 12459B is the compound referred to as "compound no. 1". See CR365. According to the evidence relied on by Child, infrared analysis was performed on sample no. 12459B-47B<sup>18</sup>, elemental analyses were performed on sample nos. 12459B-47A<sup>19</sup> and 12459B-47B,<sup>20</sup> and sample no. "285605 (12459B 47A)" was tested for anti-cancer activity. However, the testimony of inventors Child and Lin and non-inventors James, Medwid, Scheidl, Lang, Heiser and Durr is

 $<sup>^{18}\</sup>mbox{As}$  discussed above, for purposes of this final decision we will presume that sample no. 12459B-47B refers to the product labeled "B" in exhibit 1 attached to the Child declaration, i.e. bright yellow crystals having a melting point of 270-273E (CR365).

 $<sup>^{19}\</sup>mbox{As}$  discussed above, for purposes of this final decision we will presume that sample no. 12459B-47A refers to the product labeled "A" in exhibit 1 attached to the Child declaration, i.e. a beige solid having a melting point of 262E (CR365).

 $<sup>^{20}</sup>$ Both sample nos. 12459B-47A and 12459B-47B appear to have the same empirical formula. Compare CR366 and CR368.

 $<sup>^{21}\</sup>text{To}$  the extent that sample no. 285605 is the same compound as CL 285605, as discussed above, CL 285605 was assigned to sample no. 12459B-47B. See CR228; CR287,  $\P$  7.

silent as to which one of products "A" or "B" (or even "C", "D" or "E") is "compound no. 1." See KB18-19 (junior party's declarations fail to identify which sample is actually the sample called compound 1; despite difference in color and 10EC difference in melting point, we are left to draw an assumption as to whether sample A, sample B, a combination of samples A and B, or sample C, D or E is compound 1). Neither the brief nor the reply brief of junior party Child clarifies the matter. Compare Mikus, 542 F.2d at 1159-60, 191 USPQ at 574 (actual reduction to practice was not established where priority proofs were shown to be inconsistent).

For the reasons set forth below, the evidence relied on by junior party Child as a whole fails to establish that a compound within the scope of the count was actually reduced to practice prior to the critical date.

### 1. Production and recognition of compound

Junior party Child relies on the results of an infrared spectroscopy analysis of sample no. 12459B-47B and elemental analyses of sample nos. 12459B-47A and 12459B-47B to establish that a compound satisfying the limitations of the count was

produced prior to the critical date.

As discussed above, to establish an actual reduction to practice, junior party Child must prove, <u>inter alia</u>, (1) that a compound satisfying the limitations of the count was produced prior to the critical date and (2) that the inventors had contemporaneous appreciation of the compound produced.

<u>Estee Lauder</u>, 129 F.3d at 592, 44 USPQ2d at 1613; <u>Cooper v.</u>

<u>Goldfarb</u>, 154 F.3d 1321, 1331, 47 USPQ2d 1896, 1904 (Fed. Cir. 1998).

According to John C. James (CR4, ¶ 10):

I have reviewed each of Exhibits O-R and T-V [(CR20-23 and 25-27)] to compare the structural formula which is written on each Exhibit with the infrared absorption curve and confirm that the infrared curve for each structural formula is consistent with each structural formula.

However, James' conclusions that the curves are "consistent with" the structural formula provided on the spectroscopy request card alone fail to "confirm" that a compound satisfying the limitations of the count was produced (KB15; KB20). See In re Brandstadter, 484 F.2d 1395, 1406, 179 USPQ 286, 294 (CCPA 1973) ("the affidavits fail in their purpose since they recite conclusions and few facts to buttress said conclusions"); see also Rohm and Haas Co. v.

Brotech Corp., 127 F.3d 1089, 1092,

44 USPQ2d 1459, 1462 (Fed. Cir. 1997) ("Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness.").

Moreover, the James declaration fails to establish that the infrared absorption curve of sample no. 12459B-47B was "reviewed" and appreciated prior to the critical date. See generally CR1-5. See Cooper v. Goldfarb, 154 F.3d at 1331, 47 USPQ2d at 1904 (to establish an actual reduction to practice, the inventor must contemporaneously appreciate the invention at issue; subsequent testing or later recognition may not be used to show that a party had contemporaneous appreciation of the invention). Indeed, the evidence relied on by Child fails to establish when the infrared spectroscopy analysis of sample no. 12459B-47B was even completed. Although the absorption curve bears a date of June 7, 1984 (CR20), the meaning of that date has not been explained on this record.

As for the elemental analyses of sample nos. 12459B-47A and 12459B-47B, we are not convinced that elemental analysis conclusively establishes the identity of a compound. <u>See</u>

Thurston v. Wulff, 164 F.2d 612, 615, 76 USPQ 121, 124 (CCPA 1947) ("It must be emphasized that a test that agrees with the theoretical C, H and N content of a desired compound does not necessarily prove the identity of the same compound.").

Furthermore, the evidence relied on by junior party Child fails to establish that the results of the elemental analyses of sample nos. 12459B-47B and 12459B-47A were appreciated prior to the critical date. Exhibits 11 and 12 attached to the Medwid declaration (CR96 and 97) appear to report two different amounts of C, H, N, Pt and Cl for each sample, a calculated amount and an amount obtained through elemental analysis. At the very least, the evidence relied on by junior party Child fails to establish that the discrepancies between these two amounts were understood prior to the critical date. See KB16-17. <u>See Cooper</u>, 154 F.3d at 1331, 47 USPQ2d at 1904 (to establish an actual reduction to practice, the inventor must contemporaneously appreciate the invention at issue; subsequent testing or later recognition may not be used to show that a party had contemporaneous appreciation of the invention). In addition, the evidence relied on by junior party Child fails to establish that sample nos. 12459B-

47B and 12459B-47A were even analyzed for carbon, hydrogen and nitrogen prior to the critical date (KB17). Compare CR191, ¶ 13; CR192 (sample nos. 12459B-47B and 12459B-47B were analyzed for platinum and chlorine prior to June 9, 1984).

### 2. Recognition of utility

The evidence relied on by junior party Child, i.e., the declarations of Ralph G. Child (CR354-64), Durr (CR285-89) and Lang (CR218-20), further fails to establish that a compound within the scope of the count was known to have utility as an anti-cancer agent prior to September 3, 1984. See generally KB20-26.

According to Durr, one of the tests which was used at Lederle to identify anti-cancer activity was the "P 388 test" (CR285-86, ¶ 2). A copy of the protocol for the P 388 test is said to be attached to the Durr declaration as Exhibit A (CR286, ¶ 2; CR290-91). Compound "285605 (12459B 47A)" was said to have been tested for anti-cancer activity using the P 388 test. See CR287, ¶ 7; CR292.

We find that the identity of compound "285605 (12459B 47A)" has not been established. Namely, it is unclear on this record whether the notation "285605 (12459B 47A)" refers to

sample no. 12459B-47A or 12459B-47B.<sup>22</sup> According to the record in this interference, sample no. 12459B-47B was assigned CL number 285605 (CR228). However, the notation "285605 (12459B 47A)" appears to refer to sample no. 12459B-47A (CR292).<sup>23</sup> Junior party Child fails to explain this inconsistency.

Assuming arguendo that compound "285605 (12459B 47A)" does fall within the scope of the count, the evidence relied on by junior party Child fails to establish that the inventors knew, prior to the critical date, that the compound had utility as an anti-cancer agent. See KB25-26. See Estee Lauder Inc., 129 F.2d at 594-95, 44 USPQ2d at 1615 ("when testing is necessary to establish utility, there must be recognition and appreciation that the tests were successful for reduction to practice to occur").

First, Kolar argues that the protocol for the "P 388

 $<sup>^{22}\</sup>mbox{As}$  discussed above, the product labeled "A" on page 47 of notebook 12459B is described as a beige solid having a melting point of 262E (CR365). On the other hand, the product labeled "B" on page 47 of notebook 12459B is described as bright yellow crystals having a melting point of 270-273E (CR365).

 $<sup>^{23}\</sup>rm{Exhibit}$  C attached to the Durr declaration which appears to be a computer generated report of the results of a P 388 test includes data for compound "285605-47A" (CR293).

test" was not followed (KB21-22). We agree with Kolar that two multi-dose assays, each performed at a different laboratory, are not reported for the compounds tested. See CR291 ("For confirmed activity a synthetic must have two multi-dose assays (each performed at a different laboratory) that produce a T/C \$ 125%

. . . . "). Furthermore, it is unclear from exhibit B attached to the Durr declaration whether 5-fluorouracil was used as the positive control compound. See KB22; CRB12; CR291.

In addition, exhibit B attached to the Durr declaration bears the following dates: "DATE 6/20/84", (2) "Data Entered 7/27/84," (3) "A.J. Hauss 9/25/84," and (4) "9/27/84 H.L. Lindsay," two of which are after the critical date, and exhibit C bears the date "6/20/84." However, with the exception of the June 20, 1984, date, junior party Child has not explained the significance of these dates. See CB8; CR287, ¶¶ 7 and 8.

Child does state that "[p]rior to September 3, 1984, I learned that the compound which is described in Exhibit 1 had anti-cancer activity in the P 388 antileukemia test" (CR356, ¶ 4; emphasis added). Nevertheless, as discussed above, exhibit

1 attached to the Child declaration describes five products, i.e., "A," "B," "C," "D" and "E". See CR365. Therefore, reference to "the compound which is described in Exhibit 1" is ambiguous.

The August 1984 monthly report for the Infectious and Neoplastic Disease Section is equally lacking. The report is

silent as to the anti-cancer activity of compound "285605  $(12459B\ 47A)$ ." See CR223.<sup>24</sup>

## 3. <u>Independent corroboration</u>

Finally, the evidence relied on by junior party Child to establish an actual reduction to practice of a compound within the scope of the count prior to September 3, 1984, has not been independently corroborated. As discussed above, the inventors' testimony and documents, standing alone, are insufficient to prove an actual reduction to practice. Hahn, 892 F.2d at 1032, 13 USPQ2d at 1317; see also Lacotte v.

Thomas, 758 F.2d 611, 613, 225 USPQ 633, 634 (Fed. Cir. 1985); Price, 988 F.2d at 1194,

 $<sup>^{24} \</sup>text{Sample no.} \ 12459 \text{B}-47 \underline{\text{B}} \ \text{was assigned CL number CL285605}.$  See CR228.

26 USPQ2d at 1036; see also Mikus, 542 F.2d at 1153, 191 USPQ at 573 ("objective sought in requiring independent corroboration of reduction to practice of a chemical composition is to insure that the inventor actually prepared the composition"). Manifestly, there must be some evidence independent from the inventor which corroborates the actual reduction to practice. See Reese,

661 F.2d at 1228, 211 USPQ at 942 ("adoption of the 'rule of reason' has not altered the requirement that evidence of

corroboration must not depend solely on the inventor himself"). Junior party Child has failed to present such evidence.

Junior party Child offers the declarations of noninventors John C. James, Jeffrey B. Medwid, Franz Scheidl, Frederick Durr, Stanley A. Lang and Bruce Heiser as independent corroboration.<sup>25</sup> However, the testimony therein

<sup>&</sup>lt;sup>25</sup>For the first time in the reply brief, Child also relies on the declaration of Kimberly Miner to establish independent corroboration (CRB4). Arguments presented for the first time in a reply brief will not be considered. <u>See Photis v. Lunkenheimer</u>, 225 USPQ 948, 950 (Bd. Pat. Int. 1984) (matters not raised in the brief are ordinarily regarded as abandoned).

relating to an alleged actual reduction to practice of a compound within the scope of the count is gleaned solely from information obtained from the inventors. For example, Heiser received his information relating to the alleged identity of sample no. 12459B-47B from Ralph G. Child. See CR225-26, ¶ 4 (the chemist would provide Heiser with information identifying the compound, including the structural formula of the compound, its molecular formula and weight, the color of the compound, the chemist's notebook and page number which recorded the preparation of the compound, and the sample spectrum number). Lang also received his information from the inventors. See CR218-19, ¶¶ 2-4 (the inventors of the involved Child application would prepare and submit monthly reports to Lang that would be incorporated into a monthly report for the Infectious and Neoplastic Disease Section). 26

To the extent that preparation of the compounds at issue was part of an organized research program (CRB6), even the

<sup>&</sup>lt;sup>26</sup>To the extent that this report could have been circulated prior to the critical date, the report neither bears a date of circulation nor any indication that it was in fact circulated to and seen by anyone (CRB8-9). See In reSchulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) (arguments in the brief do not take the place of evidence in the record).

product of an "organized research program" requires some form of independent corroboration. See Reese, 661 F.2d at 1228, 211 USPQ at 940 ("adoption of the 'rule of reason' has not altered the requirement that evidence of corroboration must not depend solely on the inventor himself"); Berges v.

Gottstein, 618 F.2d 771, 774, 205 USPQ 691, 694 (CCPA 1980) (although facts set forth "a highly organized procedure routinely practiced," additional corroboration was provided by relevant related independent events).

Finally, for the first time in its reply brief, junior party Child relies on <u>Blicharz v. Hays</u>, 496 F.2d 603, 181 USPQ 712 (CCPA 1974), to advance a theory of corroboration based on a comparison of laboratory notebooks and its subsequently filed patent application (CRB4). Arguments presented for the first time in a reply brief will not be considered. <u>See Ernst Haas Studio, Inc.</u>, 164 F.3d at 112, 49 USPQ2d at 1379 ("An attempt is made in the Reply Brief to supply what was conspicuously omitted in the main Brief . . . . However, new arguments may not be made in a reply brief . . . and we decline to entertain the theories so proffered."). Therefore, we have not considered the argument.

### B. Compound nos. 2-7

The evidence relied on by junior party Child further fails to establish that any one of compound nos. 2-7, also alleged to fall within the scope of the count, was actually reduced to practice prior to the critical date. As discussed above, compound no. 1 was used to prepare each one of compound nos. 2-7. See KB10; CR370; CR375; CR379; CR384; CR391; CR393; see also CR223 ("platinum complex <u>la</u> reacted with a series of acids by the silver nitrate process to give the following complexes <u>lb-q</u>"). Having failed to establish, by a preponderance of the evidence, that compound no. 1 was actually reduced to practice prior to the critical date, junior party Child has likewise failed to establish an actual reduction to practice of any one of compound nos. 2-7 prior to the critical date.

### C. <u>Conclusion</u>

For the reasons set forth above, the evidence relied on by junior party Child fails to establish, by a preponderance of the evidence, that a compound within the scope of the count was actually reduced to practice prior to September 3, 1984.

Therefore, junior party Child's case for priority must fail.

Junior party Child takes issue with the fact that senior party Kolar did not cross-examine junior party's declarants or rebut certain declaration testimony. However, it is of no moment that senior party failed to cross-examine junior party Child's declarants. The initial burden is on junior party to establish, by a preponderance of the evidence, an actual reduction to practice of a compound within the scope of the count prior to the critical date. Holmwood, 948 F.2d at 1238, 20 USPQ2d at 1714; Bosies, 27 F.3d at 541-42, 30 USPQ2d at 1864. For the reasons set forth above, Child has failed to satisfy that burden.

Likewise, it is of no moment that the "Statement of Facts" section of senior party Kolar's brief may contain arguments. See CRB1. Child, as the junior party in this interference, bears the initial burden of establishing priority by a preponderance of the evidence. Holmwood, 948 F.2d at 1238, 20 USPQ2d at 1714; Bosies, 27 F.3d at 541-42, 30 USPQ2d at 1864. Manifestly, if the junior party has not met

its initial burden of proof, the senior party will prevail in an interference regardless of whether or not it has even filed an opposition brief. Fitch v. Cooper, 139 USPQ 382, 382 (Bd. Pat. Int. 1962) (notwithstanding uncontested nature of the case, the senior party is still presumed to be the first inventor, and the burden of proof rests upon the junior party to overcome this presumption). Accordingly, senior party's brief will not be returned pursuant to 37 CFR § 1.618 (1993).

# Issues (2) and (8)

With respect to senior party Kolar's allegations concerning abandonment, suppression and concealment, for the reasons set forth above, we have not found an actual reduction to practice of a compound within the scope of the count prior to September 3, 1984. "[W]ithout an actual reduction to practice there is no invention in existence which can be abandoned, suppressed, or concealed." Peeler v. Miller, 535 F.2d 647, 651, 190 USPQ 117, 120. Therefore, issues (2) and (8) are moot.

# Motion to strike rebuttal testimony of Kolar; <u>Issues (3)-(5), (9) and (10)</u>

Since it was not necessary to address the rebuttal testimony of Dr. Cenek Kolar, the motion to strike that

testimony (Paper Nos. 63 and 64) is <u>dismissed</u>. Furthermore, issues (3)-(5) raised by junior party Child in its brief and issues (9) and (10) raised by senior party Kolar in its brief relating to the rebuttal testimony of Dr. Kolar are moot.

#### <u>Judgment</u>

Judgment as to Count 1, the sole count at issue, is entered against junior party Ralph G. Child, Panayota Bitha, Joseph J. Hlavka and Yang-I Lin based on both priority and patentability. Ralph G. Child, Panayota Bitha, Joseph J. Hlavka and Yang-I Lin are not entitled to a patent containing claims 2-12, 33 and 34 which correspond to Count 1.

Judgment as to Count 1 is awarded in favor of senior party Cenek Kolar, Hans P. Kraemer and Konrad Dehmel. On the record before the Patent and Trademark Office in this interference,

<sup>&</sup>lt;sup>27</sup>Kolar's motion under 37 CFR § 1.633(a) for judgment on the ground that Child's claim 33 corresponding to the count is unpatentable to Child under 35 U.S.C. § 112 was granted in a decision on motions mailed June 2, 1992 (Paper No. 46). Since Child did not seek review of that decision in its brief at final hearing, judgment is also properly entered against junior party Child based on unpatentability.

Cenek Kolar, Hans P. Kraemer and Konrad Dehmel are entitled to their patent containing claim 1 which corresponds to Count 1.

MARY F. DOWNEY	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
TEDDY S. GRON	)	APPEALS AND
Administrative Patent Judge	)	INTERFERENCES
	)	
	)	
	)	
ADRIENE LEPIANE HANLON	)	
Administrative Patent Judge	)	

ALH:svt

# Counsel for Child et al.:

James V. Costigan HEDMAN, GIBSON & COSTIGAN, P.C. 1185 Avenue of the Americas New York, NY 10036

Counsel for Kolar et al.:

William F. Lawrence FROMMAR LAWRENCE HAUG LLP 745 Fifth Avenue New York, NY 10151